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EXAMINER

LI, BAO Q

ART UNIT PAPER NUMBER

1648

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

10/003,035

Applicant(s)

WANG, DANHER

Examiner

Bao Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-93 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-93 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Claims 1-93 are pending.

#### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, 22-24 and 37-46, drawn to a recombinant adenovirus carrying an HIV envelope antigen and an immunostimulatory sequence, classified in class 435, subclass 320.1.

- 1). The envelope antigen is gp160,
- 2). The envelope antigen is gp120,
- 3). The envelope antigen is gp40.

Alternatively, please select one of envelope protein from group consisting of

- 4). SEQ ID NO: 14,
- 5). SEQ ID NO: 16,
- 6). SEQ ID NO: 20,
- 7). SEQ ID NO: 21,
- 8). SEQ ID NO: 22,
- 9). SEQ ID NO: 23,
- 10). SEQ ID NO: 24.

This is not the species election because each single protein having different structures that required different search and exhibit different patentable weights.

Upon election group I, a further restriction of a regulatory protein is required under 35 U.S.C. 121:

- i). tat,
- ii). Vif,
- iii). Nef
- iv). Rev.

This is not the species election because each single protein having different structures that require different searches

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- II. Claims 1, 25-36 and 37-46, drawn to a recombinant adenovirus carrying a HIV gag gene product, a protease of HIV and an immunostimulatory sequence, classified in class 424, subclass 233.1.

Upon election group III, a further election of one single gag protein is required under 35 U.S.C. 121:

9A). p17/24,

9C). p17,

9D). p24,

Or alternatively, please further selection of the following gag protein sequences:

9E). SEQ ID NO: 34,

9F). SEQ ID NO: 35,

9G). SEQ ID NO: 36,

9H). SEQ ID NO: 40,

9I). SEQ ID NO: 41,

9J). SEQ ID NO: 42,

9K). SEQ ID NO: 46,

9L). SEQ ID NO: 47,

9M). SEQ ID NO: 48.

This is not the species election because each single protein having different structure that requires different search and has different patentable weight.

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III. Claims 47-57, 61-66 and 86, drawn to a recombinant adenovirus carrying a first HIV antigens under control of a first promoter and second HIV antigen under the control of a second promoter, classified in class 424, subclass 202.1.

Upon election group IV, a further restriction of an HIV antigen is required under 35 U.S.C. 121:

2A). The envelope antigen is gp160,

2B). The envelope antigen is gp120,

2C). The envelope antigen is gp40.

Alternatively, please select one of envelope protein from group consisting of

2D). SEQ ID NO: 14,

2E). SEQ ID NO: 16,

2F). SEQ ID NO: 20,

2G). SEQ ID NO: 21,

2H). SEQ ID NO: 22,

2I). SEQ ID NO: 23,

2J). SEQ ID NO: 24.

This is not the species election because each single protein having different structures that required different search and exhibit different patentable weights.

Upon election group I, a further restriction of a regulatory protein is required under 35 U.S.C. 121:

3A). tat,

3B). Vif,

3C). Nef

3D). Rev.

This is not the species election because each single protein having different structures that require different searches and exhibit different patentable weights.

IV. Claims 47, 57-66 and 86, drawn to a recombinant adenovirus carrying a first HIV antigens under control of a first promoter and second HIV antigen under the control of a second promoter, wherein the antigens are selected from multiple V3 loops of different glades, classified in class 424, subclass 202.1.

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Upon election group V, a further restriction/election of V3 loop sequences is required under 35 U.S.C. 121:

- 6A). SEQ ID NO: 25,
- 6B). SEQ ID NO: 26,
- 6C). SEQ ID NO: 27,
- 6D). SEQ ID NO: 28,
- 6E). SEQ ID NO: 29,
- 6F). SEQ ID NO: 30,
- 6G). SEQ ID NO: 31.

This is not the species election because different combination V3 sequence has different structure that requires different searches and exhibit different patentable weights.

V. Claims 47 and 67-86, drawn to recombinant adenovirus carrying two gag gene products of HIV, classified in class 424, subclass 199.1.

Upon election group VI, a further election of one single gag protein is required under 35 U.S.C. 121:

- 9A). p17/24,
- 9C). p17,
- 9D). p24,

Or alternatively, please further selection of the following gag protein sequences:

- 9E). SEQ ID NO: 34,
- 9F). SEQ ID NO: 35,
- 9G). SEQ ID NO: 36,
- 9H). SEQ ID NO: 40,
- 9I). SEQ ID NO: 41,
- 9J). SEQ ID NO: 42,
- 9K). SEQ ID NO: 46,
- 9L). SEQ ID NO: 47,
- 9M). SEQ ID NO: 48.

This is not the species election because each single protein having different structure that requires different search and has different patentable weight.

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- VI. Claims 87-91, drawn to a method for enhancing the immunity of host to HIV infection by using a recombinant adenovirus plus an immunostimulatory cytokine, classified in class 424, subclass 9.2.
- VII. Claims 92-93, drawn to a method for enhancing the immunity of host to HIV infection by using a recombinant adenovirus, classified in class 514, subclass 44.

**The inventions are distinct, each from the other because of the following reasons:**

Inventions I-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to structurally different products, e.g. the product of group I is a adenovirus vector comprising a HIV envelope protein antigen, whereas the product of group II is an adenovirus vector comprising a HIV gag protein antigen.

Inventions VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to structurally different methods by using structurally different products that produce different functions, e.g. the method of group V uses an adenovirus vector carrying an heterologous antigen plus an immunostimulatory molecule, whereas the method of group VI only uses an adenovirus vector carrying an antigen.

Inventions I and VII are related as process of using and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be practiced with materially different product or (2) that the product as claimed can be practiced by another and materially different process (MPEP § 806.05(f)). In the instant case, the process as claimed can be practiced with another and materially different product, such as an isolated recombinant protein of HIV envelope protein gp 120, rather than an adenovirus vector.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for one of the Groups are not required for another one of the Groups, restriction for examination purposes as indicated is proper

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This application contains claims directed to the following patentably distinct species of the claimed invention.

Species of promoter: 1A). CMV promoter, 1B).SV40 promoter, 1C). Retrovirus LTR, 1D). chicken cytoplasmic  $\beta$ -actin proctor.

Species of cytokine: 2A). IL-2 ; 2B). IL-4 ; 2C).IL-12, 2D).  $\beta$ -interferon,  $\gamma$ -interferon, 2E).GCSF, 2F).GM-CSF.

Species of administrations: 3A). intramuscular injection, 3B). Intratracheally injection, 3C). Suncutaneously injection, 3D). Intranasally administration, 3E). Intradermally injection, 3F). rectaly administration, 3G).Orally administration, 3H). Parentally administration.

Species of HIV glades: 4A). HIV glad A, 4B). HIA glad B, 4C). HIV gladC, 4D). HIV glad D, 4E). HIV glad E, 4F). HIV glad F, 4G). HIV glad G.

Species of HIV strains: 5A). BH10, 5B). pNL4-3.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, for species of promoters, claims 42 and 85, are generic. For species of cytokines, clams 44 and 82 are generic. For the administration, claim 88 is generic. For the HIV glade, claims 5 and 16 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).



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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li



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September 21, 2003